

and may be used to identify the alveolar opening and closing pressure levels of the lung. This technique has the advantage that an invasive arterial line is not necessary. Rather, this parameter may be measured outside the body and may be used as a feedback signal for automatic artificial ventilation (see page 6, lines 9-18 of the specification).

More particularly, an alveolar opening due to a subsequent increase of ventilation pressure may be detected by a large increase in  $SO_2$ . Similarly, an alveolar collapse due to a reduction of ventilation pressure may be detected by a decrease in  $SO_2$  (see page 6, lines 19-28 of the specification).

The technique defined by dependent claims 2-5 and 15 deals with the problem that, due to the direct measurement of  $SO_2$ , the oxygen saturation may temporarily reach rather low values which could cause life threatening situations (see page 6, lines 29-31 of the specification).

The technique defined by claims 2-5 and 15 is to provide an additional feedback control for the oxygen saturation  $SO_2$  by controlling the inspiratory oxygen fraction  $fiO_2$  correspondingly. This technique corresponds to Fig. 16 of the application and is explained at page 7, lines 1-15 and page 21, line 21 to page 22, line 5 of the specification.

The technique defined by claims 2-5 and 15 is not contradictory with respect to independent claims 1 and 14, but constitutes a more specific embodiment, which is explained in more detail as follows. Fig. 16 shows a feedback control loop according to dependent claims 2-5 and 15, in which the oxygen saturation  $SO_2$  is fed back to a controller for controlling the inspiratory oxygen fraction  $fiO_2$ . The controller operates such that the oxygen saturation  $SO_2$  is **approximately** equal to the reference value  $SO_{2, \text{ soll.}}$ . If there is no change of the oxygen saturation  $SO_2$ , the inspiratory oxygen fraction  $fiO_2$  does not change. However, if the oxygen saturation  $SO_2$  changes, the controller controls against this change and applies a corresponding inspiratory oxygen fraction  $fiO_2$ . Thus, changes of  $SO_2$  are transformed to changes of the controller signal  $fiO_2$ , which are directly related to each other by the control function implemented in the controller.

As a result, claims 1 and 14 read on the control loop shown in Fig. 16, because the airway pressure level at which alveolar opening or closing occurs is still determined from the observation of the resulting course of the measured oxygen saturation  $SO_2$ . Additionally, dependent claims 2-5 and 15 also read on the control loop according to Fig. 16, because due to the control loop the airway pressure level may be determined from the resulting course of the

adjusted (i.e., adjusted by the controller) inspiratory oxygen fraction  $fiO_2$ , which in turn is a function of the resulting course of the measured oxygen saturation  $SO_2$ .

The logical link between independent claims 1 and 14 on the one hand and dependent claims 2-5 and 15 on the other is the phrase "approximately equal" which is clarified by the description at page 7, lines 1-15 and page 21, line 21 to page 22, line 5, that there is still a resulting course of oxygen saturation, but which is now within certain limits due to the closed loop control in order to avoid life threatening situations for the patient.

Based upon the above clarification and discussion, it is the Applicants' position that claims 2-5 and 15 are in full compliance with 35 U.S.C. §112, second paragraph. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 1, 6-14, 16 and 17 have been allowed. No prior art has been applied against claims 1-17. Accordingly, claims 1-17 are in condition for allowance.

### CONCLUSION

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this response, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By: William R. McClellan  
William R. McClellan, Reg. No. 29,409  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 720-3500